

REMARKS

Reconsideration of this application is requested.

Claims 43-58 are pending. Claims 20, 22-30 and 32-42, have been canceled, without prejudice.

New claim 43 corresponds to canceled claim 20 but has been amended to delete the term "secondary" and replace it with "which occurs in but does not originate from the central nervous system of a human", to more clearly define the tumor. New claims 44 to 46 correspond to canceled claims 22 to 24, respectively. New claim 47 corresponds to canceled claim 2, however, this claim has now been amended to specify modification by deletion. New claims 48 to 51 correspond essentially to canceled claims 26 to 29. New claim 52 relates to the treatment of a melanoma cancer in a human. This is supported by the application as filed by, for instance, example 1 page 18. The dependent claims 53-58 mirror new claims 44 to 51. No new matter has been added.

The separate Section 112, first paragraph rejections of claims 20, 22, 24-30, 32-34 and 36-42, and 25-29 and 36-39, stated on pages 3-4 of the Office Action of February 2, 1999 (Paper No. 16) are moot in view of the above. The applicants respectfully submit the claims are supported by an enabling disclosure and the Examiner is requested to consider the following, and attached, in this regard.

At ¶7 of Paper No. 16, the Examiner has objected to all of the previously pending claims as not providing enough information as to allow the skilled person to work the invention across the entire scope of the claims. The applicants respectfully submit that the specification, as filed,

provides details of how to make and use the claimed invention. Moreover, the ordinarily skilled artisan would have been able to use the general knowledge in the art, such as the HSV sequence and/or molecular biological techniques, available at the time of the present invention, as further alternatives to the exemplified methods of the present specification. The Examiner is urged to appreciate that the standard for enablement under 35 U.S.C. § 112, first paragraph, is that one of ordinary skill in the art would have been able to use the description of the application to make and use the claimed invention. "An invention need not, however, explain every detail since he is speaking to those skilled in the art" DeGeorge v. Bernier, 226 USPQ 758, 762 (Fed. Cir 1985) (copy attached).

Moreover, in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988) (copy attached), the Federal Circuit Court of Appeals has held that engagement in experimentation to practice a claimed invention does not render the disclosure non-enabling as long as the experimentation required in not "undue". The court stated that:

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness. The test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Id. at 1404, citing In re Jackson, 217 USPQ at 807.

The applicants submit that in the present case, the applicants have provided details of the background to the present invention including details of what would be considered common general knowledge to a person of ordinary skill in this area. In other words, the application provides details of the sequence of the HSV-1 virus, e.g. McGeoch et al J. Gen Virol 69: 153 1-1574, 1988. The application then describes various other mutants of HSV which have been

described in the prior art, e.g. R3616 (page 3). Although the various molecular biological techniques required to produce mutants within the scope of the present claims would be considered common general knowledge, the applicants also provide detailed information as to how to produce a particular mutant, namely, 1716. It is submitted that this information would be more than sufficient for the ordinarily skilled person to produce other mutants within the scope of the present invention, without undue experimentation.

In ¶ 8 of Paper No. 16, the Examiner has objected to now canceled claim 25, and dependent claims, and now canceled claim 36 and dependent claims. This rejection is moot, in view of the above. The applicants respectfully submit that the ordinarily skilled person would have been able to modify the HSV by deletion, as claimed, without any due difficulty following the teaching in the art (common general knowledge) and the teachings of US 5,328,688 and USSN 08/766840 which has been allowed.

The pending claims are submitted to be supported by an enabling disclosure.

The Section 103 rejection of claims 20, 22, 24-30, 32-34 and 36-42 over Market (Neurosurgery 32, 597-603) in view of WO 92/13943 is moot in view of the above. The pending claims are submitted to be patentable over the cited art and the Examiner is requested to consider the following in this regard.

Market et al teaches that HSV-1 mutant R3616 which has non-functional γ 34.5 genes and reduced neurovirulence, is effective against intracranial gliomas in mice, i.e. the mutant prolonged survival time without producing premature death from encephalitis. Gliomas are benign (therefore by definition not metastatic/secondary) tumors derived from one of the various types of cells that form the interstitial tissue of the brain, spinal cord, pineal gland, posterior

pituitary gland and retina. Gliomas originate in the CNS and therefore do not fall into the specific category of tumors being the subject of the present invention.

The question therefore is whether the skilled person would immediately assume that a mutant virus effective against glioma would be equally effective against a metastatic tumor which occurs in but does not originate from the CNS. It is submitted that the skilled person would not assume that both distinct forms of tumors could be treated in a similar fashion. Indeed, the skilled person would not carry out such treatment with any, let alone reasonable, expectation of success. The applicants attach hereto a SCRIIP article which illustrates that the FDA do not consider that gliomas and metastatic tumors (melanoma) can be assumed to be treated similarly with any expectation of success.

WO 92/13942 discloses the production of a Herpes Simplex Virus-1 mutant virus. However, it does contain any disclosure of the use of such HSV- 1 deletion variants to treat cancer. Therefore, if the teaching of this document were to be considered with that of Market et al, it would provide little more than an alternative to R36 16 to treat gliomas. The Examiner has not provided any evidence of why the ordinarily skilled person would have been motivated with any expectation of success to use either of these HSV- 1 mutants to treat metastatic tumors which are distinctly different from gliomas. The applicants respectfully submit therefore that the Examiner has not established a *prima facie* case of obviousness.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



B.J. Sadoff
Reg. No. 36,663

BJS:
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4091
Facsimile: (703) 816-4100

of Law will be entered on the same date herewith.

ORDER AND JUDGMENT

In accordance with the Findings of Fact and Conclusions of Law entered on the same date herewith,

IT IS HEREBY ORDERED AND ADJUDGED, as follows:

1. The Nolan patent (No. 4,506,189), issued on March 19, 1985, is a valid patent.
2. By the manufacture, production, sale and distribution of its SAF-T-COTE fluorescent lamp, Trojan has infringed the Nolan patent.
3. By virtue of this infringement, Shat-R-Shield is entitled to injunctive relief. Trojan shall immediately cease and desist from the manufacture, production, sale and distribution of the SAF-T-COTE fluorescent lamp.
4. Trojan shall recall all the SAF-T-COTE fluorescent lamps sold to and still in the possession of its customers.
5. The Court having determined that Trojan's infringement was not willful and wanton, Shat-R-Shield is not entitled to treble damages.
6. Shat-R-Shield shall have no accounting for monetary damages.
7. The Court having found that this is not an exceptional case, Shat-R-Shield is not entitled to its attorney's fees.
8. All claims having been resolved as to all parties herein, this action is now DISMISSED and STRICKEN from the docket.
9. There being no just reason for delay, this is a FINAL and APPEALABLE Order and Judgment.

Court of Appeals, Federal Circuit

In re Wands

No. 87-1454

Decided September 30, 1988

PATENTS

1. Patentability/Validity — Adequacy of disclosure (§115.12)

Data disclosed in application for immunoassay method patent, which shows that applicants screened nine of 143 cell lines developed for production of antibody necessary to practice invention, stored remainder of said cell lines, and found that four out of nine cell lines screened produced antibody falling within limitation of claims, were erroneously

interpreted by Board of Patent Appeals and Interferences as failing to meet disclosure requirements of 35 USC 112, since board's characterization of stored cell lines as "failures" demonstrating unreliability of applicants' methods was improper in view of fact that such unscreened cell lines prove nothing concerning probability of success of person skilled in art attempting to obtain requisite antibodies using applicants' methods.

2. Patentability/Validity — Adequacy of disclosure (§115.12)

Disclosure in application for immunoassay method patent does not fail to meet enablement requirement of 35 USC 112 by requiring "undue experimentation," even though production of monoclonal antibodies necessary to practice invention first requires production and screening of numerous antibody producing cells or "hybridomas," since practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one "experiment" is not simply screening of one hybridoma but rather is entire attempt to make desired antibody, and since record indicates that amount of effort needed to obtain desired antibodies is not excessive, in view of applicants' success in each attempt to produce antibody that satisfied all claim limitations.

Appeal from decision of Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent of Jack R. Wands, Vincent R. Zurawski, Jr., and Hubert J. P. Schoemaker, serial number 188,735. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicants appeal. Reversed; Newman, J., concurring in part and dissenting in part in separate opinion.

Jorge A. Goldstein, of Saidman, Sterne, Kessler & Goldstein (Henry N. Wixon, with them on brief), Washington, D.C., for appellant.

John H. Raubitschek, associate solicitor (Joseph F. Nakamura and Fred E. McKelvey, with him on brief), PTO, for appellee. Before Smith, Newman, and Bissell, circuit judges.
Smith, J.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) affirming the rejection of all remaining claims in appellant's application for a patent, serial No. 188,735, entitled "Immunoassay Utilizing Monoclonal High Affinity IgM

Antibodies," which was filed September 19, 1980.¹ The rejection under 35 U.S.C. §112, first paragraph, is based on the grounds that appellant's written specification would not enable a person skilled in the art to make the monoclonal antibodies that are needed to practice the claimed invention without undue experimentation. We reverse.

I. Issue

The only issue on appeal is whether the board erred, as a matter of law, by sustaining the examiner's rejection for lack of enablement under 35 U.S.C. §112, first paragraph, of all remaining claims in appellants' patent application, serial No. 188,735.

II. Background

A. The Art.

The claimed invention involves immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype. *Antibodies* are a class of proteins (immunoglobulins) that help defend the body against invaders such as viruses and bacteria. An antibody has the potential to bind tightly to another molecule, which molecule is called an antigen. The body has the ability to make millions of different antibodies that bind to different antigens. However, it is only after exposure of an antigen that a complicated *immune response* leads to the production of antibodies against that antigen. For example, on the surface of hepatitis B virus particles there is a large protein called *hepatitis B surface antigen* (HBsAg). As its name implies, it is capable of serving as an antigen. During a hepatitis B infection (or when purified HBsAg is injected experimentally), the body begins to make antibodies that bind tightly and specifically to HBsAg. Such antibodies can be used as reagents for sensitive diagnostic tests (e.g., to detect hepatitis B virus in blood and other tissues, a purpose of the claimed invention). A method for detecting or measuring antigens by using antibodies as reagents is called an *immunoassay*.

Normally, many different antibodies are produced against each antigen. One reason for this diversity is that different antibodies are produced that bind to different regions (determinants) of a large antigen molecule such as HBsAg. In addition, different anti-

bodies may be produced that bind to the same determinant. These usually differ in the tightness with which they bind to the determinant. *Affinity* is a quantitative measure of the strength of antibody-antigen binding. Usually an antibody with a higher affinity for an antigen will be more useful for immunological diagnostic tests than one with a lower affinity. Another source of heterogeneity is that there are several immunoglobulin classes or *isotypes*. Immunoglobulin G (IgG) is the most common isotype in serum. Another isotype, immunoglobulin M (IgM), is prominent early in the immune response. IgM molecules are larger than IgG molecules, and have 10 antigen-binding sites instead of the 2 that are present in IgG. Most immunoassay methods use IgG, but the claimed invention uses only IgM antibodies.

For commercial applications there are many disadvantages to using antibodies from serum. Serum contains a complex mixture of antibodies against the antigen of interest within a much larger pool of antibodies directed at other antigens. There are available only in a limited supply that ends when the donor dies. The goal of monoclonal antibody technology is to produce an unlimited supply of a single purified antibody.

The blood cells that make antibodies are *lymphocytes*. Each lymphocyte makes only one kind of antibody. During an immune response, lymphocytes exposed to their particular antigen divide and mature. Each produces a *clone* of identical daughter cells, all of which secrete the same antibody. Clones of lymphocytes, all derived from a single lymphocyte, could provide a source of a single homogeneous antibody. However, lymphocytes do not survive for long outside of the body in cell culture.

Hybridoma technology provides a way to obtain large numbers of cells that all produce the same antibody. This method takes advantage of the properties of *myeloma* cells derived from a tumor of the immune system. The cancerous myeloma cells can divide indefinitely in vitro. They also have the potential ability to secrete antibodies. By appropriate experimental manipulations, a myeloma cell can be made to fuse with a lymphocyte to produce a single hybrid cell (hence, a hybridoma) that contains the genetic material of both cells. The hybridoma secretes the same antibody that was made by its parent lymphocyte, but acquires the capability of the myeloma cell to divide and grow indefinitely in cell culture. Antibodies produced by a clone of hybridoma cells (i.e., by hybridoma

¹ *In re Wands*, Appeal No. 673-76 (Bd. Pat. App. & Int. Dec. 30, 1986).

cells that are all progeny of a single cell) are called monoclonal antibodies.²

B. The Claimed Invention.

The claimed invention involves methods for the immunoassay of HBsAg by using high-affinity monoclonal IgM antibodies. Jack R. Wands and Vincent R. Zurawski, Jr., two of the three coinventors of the present application, disclosed methods for producing monoclonal antibodies against HBsAg in United States patent No. 4,271,145 (the '145 patent), entitled "Process for Producing Antibodies to Hepatitis Virus and Cell Lines Therefor," which patent issued on June 2, 1981. The '145 patent is incorporated by reference into the application on appeal. The specification of the '145 patent teaches a procedure for immunizing mice against HBsAg, and the use of lymphocytes from these mice to produce hybridomas that secrete monoclonal antibodies specific for HBsAg. The '145 patent discloses that this procedure yields both IgG and IgM antibodies with high-affinity binding to HBsAg. For the stated purpose of complying with the best mode requirement of 35 U.S.C. §112, first paragraph, a hybridoma cell line that secretes IgM antibodies against HBsAg (the 1F8 cell line) was deposited at the American Type Culture Collection, a recognized cell depository, and became available to the public when the '145 patent issued.

The application on appeal claims methods for immunoassay of HBsAg using monoclonal antibodies such as those described in the '145 patent. Most immunoassay methods have used monoclonal antibodies of the IgG isotype. IgM antibodies were disfavored in the prior art because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Appellants found that their monoclonal IgM antibodies could be used for immunoassay of HBsAg with unexpectedly high sensitivity and specificity. Claims 1, 3, 7, 8, 14, and 15 are drawn to methods for the immunoassay of HBsAg using high-affinity IgM monoclonal antibodies. Claims 19 and 25-27 are for chemically modified (e.g., radioactively labeled) monoclonal IgM antibodies used in the assays. The broadest method claim reads:

1. An immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg)

determinants which comprises the steps of:

contacting a test sample containing said substance comprising HBsAg determinants with said antibody; and

determining the presence of said substance in said sample;

wherein said antibody is a monoclonal high affinity IgM antibody having a binding affinity constant for said HBsAg determinants of at least 10^9 M⁻¹.

Certain claims were rejected under 35 U.S.C. §103; these rejections have not been appealed. Remaining claims 1, 3, 7, 8, 14, 15, 19, and 25-27 were rejected under 35 U.S.C. §112, first paragraph, on the grounds that the disclosure would not enable a person skilled in the art to make and use the invention without undue experimentation. The rejection is directed solely to whether the specification enables one skilled in the art to make the monoclonal antibodies that are needed to practice the invention. The position of the PTO is that data presented by Wands show that the production of high-affinity IgM anti-HBsAg antibodies is unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies.

III. Analysis

A. Enablement by Deposit of Micro-organisms and Cell Lines.

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention. "Patents *** are written to enable those skilled in the art to practice the invention." A patent need not disclose what is well known in the art.³ Although we review underlying facts found by the board under a "clearly erroneous" standard,⁴ we review enablement as a question of law.⁵

Where an invention depends on the use of living materials such as microorganisms or

² For a concise description of monoclonal antibodies and their use in immunoassay see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1368-71, 231 USPQ 81, 82-83 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 1606 (1987).

³ *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

⁴ *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

⁵ *Coleman v. Dines*, 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed. Cir. 1985).

⁶ *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268, 229 USPQ 805, 810 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 875 (1987); *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6, 220 USPQ 592, 599 n.6 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 [225 USPQ 232] (1984).

cultured cells, it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of a written disclosure. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.⁷ Administrative guidelines and judicial decisions have clarified the conditions under which a deposit of organisms can satisfy the requirements of section 112.⁸ A deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public.⁹ Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials.¹⁰

In addition to satisfying the enablement requirement, deposit of organisms also can be used to establish the filing date of the application as the prima facie date of invention,¹¹ and to satisfy the requirement under 35 U.S.C. §114 that the PTO be guaranteed access to the invention during pendency of

the application.¹² Although a deposit may serve these purposes, we recognized, in *In re Lundak*,¹³ that these purposes, nevertheless, may be met in ways other than by making a deposit.

A deposit also may satisfy the best mode requirement of section 112, first paragraph, and it is for this reason that the 1F8 hybridoma was deposited in connection with the '145 patent and the current application. Wands does not challenge the statements by the examiner to the effect that, although the deposited 1F8 line enables the public to perform immunoassays with antibodies produced by that single hybridoma, the deposit does not enable the generic claims that are on appeal. The examiner rejected the claims on the grounds that the written disclosure was not enabling and that the deposit was inadequate. Since we hold that the written disclosure fully enables the claimed invention, we need not reach the question of the adequacy of deposits.

B. Undue Experimentation.

Although inventions involving microorganisms or other living cells often can be enabled by a deposit,¹⁴ a deposit is not always necessary to satisfy the enablement requirement.¹⁵ No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.¹⁶ Whether the specification in an application involving living cells (here, hybridomas) is enabled without a deposit must be decided on the facts of the particular case.¹⁷

Appellants contend that their written specification fully enables the practice of

⁷ *In re Argoudelis*, 434 F.2d 1390, 1392-93, 168 USPQ 99, 101-02 (CCPA 1970).

⁸ *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985); *Feldman v. Aunstrup*, 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), cert. denied, 424 U.S. 912 (1985 USPQ 720) (1976); Manual of Patent Examining Procedure (MPEP) 608.01 (p)(C) (5th ed. 1983, rev. 1987). See generally Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. Pat. Trademark Off. Soc'y 569 (1985).

⁹ *In re Jackson*, 217 USPQ 804, 807-08 (Bd. App. 1982) (strains of a newly discovered species of bacteria isolated from nature); *Feldman*, 517 F.2d 1351, 186 USPQ 108 (uncommon fungus isolated from nature); *In re Argoudelis*, 434 F.2d at 1392, 168 USPQ at 102 (novel strain of antibiotic-producing microorganism isolated from nature); *In re Kropp*, 143 USPQ 148, 152 (Bd. App. 1959) (newly discovered microorganism isolated from soil).

¹⁰ *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (genetically engineered bacteria where the specification provided insufficient information about the amount of time and effort required); *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (unique cell line produced from another cell line by mutagenesis).

¹¹ *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman*, 517 F.2d at 1355, 186 USPQ at 113; *In re Argoudelis*, 434 F.2d at 1394-96, 168 USPQ at 103-04 (Baldwin, J. concurring).

¹² *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman*, 517 F.2d at 1354, 186 USPQ at 112.

¹³ *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95-96.

¹⁴ *In re Argoudelis*, 434 F.2d at 1393, 168 USPQ at 102.

¹⁵ *Tabuchi v. Nubel*, 559 F.2d 1183, 194 USPQ 521 (CCPA 1977).

¹⁶ *Id.* at 1186-87, 194 USPQ at 525; *Merck & Co. v. Chase Chem. Co.*, 273 F.Supp. 68, 77, 155 USPQ 139, 146 (D.N.J. 1967); *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F.2d 400, 403-06, 12 USPQ 47, 50-53 (D. Del. 1931), aff'd, 61 F.2d 1041, 15 USPQ 237 (3d Cir. 1932), cert. denied, 288 U.S. 614 (1933); MPEP 608.01(p)(C) ("No problem exists when the microorganisms used are known and readily available to the public.").

¹⁷ *In re Jackson*, 217 USPQ at 807; see *In re Metcalfe*, 410 F.2d 1378, 1382, 161 USPQ 789, 792 (CCPA 1969).

their claimed invention because the monoclonal antibodies needed to perform the immunoassays can be made from readily available starting materials using methods that are well known in the monoclonal antibody art. Wands states that application of these methods to make high-affinity IgM anti-HBsAg antibodies requires only routine screening, and that does not amount to undue experimentation. There is no challenge to their contention that the starting materials (i.e., mice, HBsAg antigen, and myeloma cells) are available to the public. The PTO concedes that the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against HBsAg were either well known in the monoclonal antibody art or adequately disclosed in the '145 patent and in the current application. This is consistent with this court's recognition with respect to another patent application that methods for obtaining and screening monoclonal antibodies were well known in 1980.¹⁸ The sole issue is whether, in this particular case, it would require undue experimentation to produce high-affinity IgM monoclonal antibodies.

Enablement is not precluded by the necessity for some experimentation such as routine screening.¹⁹ However, experimentation needed to practice the invention must not be undue experimentation.²⁰ "the key word is 'undue,' not 'experimentation.'"²¹

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *Ansul Co. v. Uniroyal, Inc.* [448 F.2d 872, 878-79; 169 USPQ 759, 762-63 (2d Cir. 1971), *cert. denied*, 404 U.S. 1018 [172 USPQ 257] (1972)]. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the

direction in which the experimentation should proceed * * *.²²

The term "undue experimentation" does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.²³ Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. The board concluded that undue experimentation would be needed to practice the invention on the basis of experimental data presented by Wands. These data are not in dispute. However, Wands and the board disagree strongly on the conclusion that should be drawn from that data.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*.²⁴ They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.²⁵

In order to understand whether the rejection was proper, it is necessary to discuss further the methods for making specific monoclonal antibodies. The first step for making monoclonal antibodies is to immunize an animal. The '145 patent provides a detailed description of procedures for immunizing a specific strain of mice against HBsAg. Next the spleen, an organ rich in lymphocytes, is removed and the lymphocytes are separated from the other spleen cells. The lymphocytes are mixed with myeloma cells, and the mixture is treated to cause a few of the cells to fuse with each other. Hybridoma cells that secrete the desired antibodies then must be isolated from the enormous number of other cells in the mixture. This is done through a series of screening procedures.

The first step is to separate the hybridoma cells from unfused lymphocytes and myeloma cells. The cells are cultured in a medi-

¹⁸ *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94.

¹⁹ *Id.*; *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984); *In re Angstadt*, 537 F.2d at 502-504, 190 USPQ at 218; *In re Geerdes*, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *Mineral Separation, Ltd. v. Hyde*, 242 U.S. 261, 270-71 (1916).

²⁰ *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94; *W.L. Gore*, 721 F.2d at 1557, 220 USPQ at 316; *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring).

²¹ *In re Angstadt*, 537 F.2d at 504, 190 USPQ at 219.

²² *In re Jackson*, 217 USPQ at 807.

²³ See *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94; *Atlas Powder*, 750 F.2d at 1576, 224 USPQ at 413.

²⁴ *Ex parte Forman*, 230 USPQ at 547.

²⁵ *Id.*; see *In re Colianni*, 561 F.2d at 224, 195 USPQ at 153 (Miller, J., concurring); *In re Rainer*, 347 F.2d 574, 577, 146 USPQ 218, 221 (CCPA 1965).

um in which all the lymphocytes and myeloma cells die, and only the hybridoma cells survive. The next step is to isolate and clone hybridomas that make antibodies that bind to the antigen of interest. Single hybridoma cells are placed in separate chambers and are allowed to grow and divide. After there are enough cells in the clone to produce sufficient quantities of antibody to analyze, the antibody is assayed to determine whether it binds to the antigen. Generally, antibodies from many clones do not bind the antigen, and these clones are discarded. However, by screening enough clones (often hundreds at a time), hybridomas may be found that secrete antibodies against the antigen of interest.

Wands used a commercially available radioimmunoassay kit to screen clones for cells that produce antibodies directed against HBsAg. In this assay the amount of radioactivity bound gives some indication of the strength of the antibody-antigen binding, but does not yield a numerical affinity constant, which must be measured using the more laborious Scatchard analysis. In order to determine which anti-HBsAg antibodies satisfy all of the limitations of appellants' claims, the antibodies require further screening to select those which have an IgM isotype and have a binding affinity constant of at least 10^9 M⁻¹.²⁶ The PTO does not question that the screening techniques used by Wands were well known in the monoclonal antibody art.

During prosecution Wands submitted a declaration under 37 C.F.R. §1.132 providing information about all of the hybridomas that appellants had produced before filing the patent application. The first four fusions were unsuccessful and produced no hybridomas. The next six fusion experiments all produced hybridomas that made antibodies specific for HBsAg. Antibodies that bound at least 10,000 cpm in the commercial radioimmunoassay were classified as "high binders." Using this criterion, 143 high-binding hybridomas were obtained. In the declaration, Wands stated that²⁷

* The examiner, the board, and Wands all point out that, technically, the strength of antibody-HBsAg binding is measured as *avidity*, which takes into account multiple determinants on the HBsAg molecule, rather than affinity. Nevertheless, despite this correction, all parties then continued to use the term "affinity." We will use the terminology of the parties. Following the usage of the parties, we will also use the term "high affinity" as essentially synonymous with "having a binding affinity constant of at least 10^9 M⁻¹."

* A table in the declaration presented the binding data for antibodies from every cell line. Values ranged from 13,867 to 125,204 cpm, and a

It is generally accepted in the art that, among those antibodies which are binders with 50,000 cpm or higher, there is a very high likelihood that high affinity (Ka [greater than] 10^9 M⁻¹) antibodies will be found. However, high affinity antibodies can also be found among high binders of between 10,000 and 50,000, as is clearly demonstrated in the Table.

The PTO has not challenged this statement.

The declaration stated that a few of the high-binding monoclonal antibodies from two fusions were chosen for further screening. The remainder of the antibodies and the hybridomas that produced them were saved by freezing. Only nine antibodies were subjected to further analysis. Four (three from one fusion and one from another fusion) fell within the claims, that is, were IgM antibodies and had a binding affinity constant of at least 10^9 M⁻¹. Of the remaining five antibodies, three were found to be IgG, while the other two were IgM for which the affinity constants were not measured (although both showed binding well above 50,000 cpm).

Apparently none of the frozen cell lines received any further analysis. The declaration explains that after useful high-affinity IgM monoclonal antibodies to HBsAg had been found, it was considered unnecessary to return to the stored antibodies to screen for more IgMs. Wands says that the existence of the stored hybridomas was disclosed to the PTO to comply with the requirement under 37 C.F.R. §1.56 that applicants fully disclose all of their relevant data, and not just favorable results.²⁸ How these stored hybridomas are viewed is central to the positions of the parties.

The position of the board emphasizes the fact that since the stored cell lines were not completely tested, there is no proof that any of them are IgM antibodies with a binding affinity constant of at least 10^9 M⁻¹. Thus, only 4 out of 143 hybridomas, or 2.8 percent, were *proved* to fall within the claims. Furthermore, antibodies that were proved to be high-affinity IgM came from only 2 of 10 fusion experiments. These statistics are viewed by the board as evidence that appellants' methods were not predictable or reproducible. The board concludes that Wands' low rate of demonstrated success shows that a person skilled in the art would have to

substantial proportion of the antibodies showed binding greater than 50,000 cpm. In confirmation of Dr. Wand's statement, two antibodies with binding less than 25,000 cpm were found to have affinity constants greater than 10^9 M⁻¹.

²⁸ See *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 220 USQ 98 (Fed. Cir. 1983).

engage in undue experimentation in order to make antibodies that fall within the claims.

Wands views the data quite differently. Only nine hybridomas were actually analyzed beyond the initial screening for HBsAg binding. Of these, four produced antibodies that fell within the claims, a respectable 44 percent rate of success. (Furthermore, since the two additional IgM antibodies for which the affinity constants were never measured showed binding in excess of 50,000 cpm, it is likely that these also fall within the claims.) Wands argues that the remaining 134 unanalyzed, stored cell lines should not be written off as failures. Instead, if anything, they represent partial success. Each of the stored hybridomas had been shown to produce a high-binding antibody specific for HBsAg. Many of these antibodies showed binding above 50,000 cpm and are thus highly likely to have a binding affinity constant of at least 10^9 M^{-1} . Extrapolating from the nine hybridomas that were screened for isotype (and from what is well known in the monoclonal antibody art about isotype frequency), it is reasonable to assume that the stored cells include some that produce IgM. Thus, if the 134 incompletely analyzed cell lines are considered at all, they provide some support (albeit without rigorous proof) to the view that hybridomas falling within the claims are not so rare that undue experimentation would be needed to make them.

The first four fusion attempts were failures, while high-binding antibodies were produced in the next six fusions. Appellants contend that the initial failures occurred because they had not yet learned to fuse cells successfully. Once they became skilled in the art, they invariably obtained numerous hybridomas that made high-binding antibodies against HBsAg and, in each fusion where they determined isotype and binding affinity they obtained hybridomas that fell within the claims.

Wands also submitted a second declaration under 37 C.F.R. §1.132 stating that after the patent application was submitted they performed an eleventh fusion experiment and obtained another hybridoma that made a high-affinity IgM anti-HBsAg antibody. No information was provided about the number of clones screened in that experiment. The board determined that, because there was no indication as to the number of hybridomas screened, this declaration had very little value. While we agree that it would have been preferable if Wands had included this information, the declaration does show that when appellants repeated their procedures they again obtained a hy-

brido ma that produced an antibody that fit all of the limitations of their claims.

[1] We conclude that the board's interpretation of the data is erroneous. It is strained and unduly harsh to classify the stored cell lines (each of which was proved to make high-binding antibodies against HBsAg) as failures demonstrating that Wands' methods are unpredictable or unreliable.²⁹ At worst, they prove nothing at all about the probability of success, and merely show that appellants were prudent in not discarding cells that might someday prove useful. At best, they show that high-binding antibodies, the starting materials for IgM screening and Scatchard analysis, can be produced in large numbers. The PTO's position leads to the absurd conclusion that the more hybridomas an applicant makes and saves without testing the less predictable the applicant's results become. Furthermore, Wands' explanation that the first four attempts at cell fusion failed only because they had not yet learned to perform fusions properly is reasonable in view of the fact that the next six fusions were all successful. The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would be for other antigens.

[2] When Wands' data is interpreted in a reasonable manner, analysis considering the factors enumerated in *Ex parte Forman* leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that un-

²⁹ Even if we were to accept the PTO's 2.5 percent success rate, we would not be required to reach a conclusion of undue experimentation. Such a determination must be made in view of the circumstances of each case and cannot be made solely in reference to a particular numerical cutoff.

due experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAg, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure.³⁰

IV. Conclusion

Considering all of the factors, we conclude that it would not require undue experimentation to obtain antibodies needed to practice the claimed invention. Accordingly, the rejection of Wands' claims for lack of enablement under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

Newman, J., concurring in part, dissenting in part.

A

I concur in the court's holding that additional samples of hybridoma cell lines that produce these high-affinity IgM monoclonal antibodies need not be deposited. This invention, as described by Wands, is not a selection of a few rare cells from many possible cells. To the contrary, Wands states that all monoclonally produced IgM antibodies to hepatitis B surface antigen have the desired high avidity and other favorable properties, and that all are readily preparable by now-standard techniques.

Wands states that his United States Patent No. 4,271,145 describes fully operable techniques, and is distinguished from his first four failed experiments that are referred

to in the Rule 132 affidavit. Wands argues that these biotechnological mechanisms are relatively well understood and that the preparations can be routinely duplicated by those of skill in this art, as in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987). I agree that it is not necessary that there be a deposit of multiple exemplars of a cell system that is readily reproduced by known, specifically identified techniques.

B

I would affirm the board's holding that Wands has not complied with 35 U.S.C. § 112, first paragraph, in that he has not provided data sufficient to support the breadth of his generic claims. Wands' claims on appeal include the following:

19. Monoclonal high affinity IgM antibodies immunoreactive with HBsAg determinants, wherein said antibodies are coupled to an insoluble solid phase, and wherein the binding affinity constant of said antibodies for said HBsAg determinants is at least 10^9 M⁻¹.

26. Monoclonal high affinity IgM antibodies immunoreactive with hepatitis B surface antigen.

Wands states that he obtained 143 "high binding monoclonal antibodies of the right specificity" in the successful fusions; although he does not state how they were determined to be high binding or of the right specificity, for Wands also states that only nine of these 143 were tested.

Of these nine, four (three from one fusion and one from another fusion) were found to have the claimed high affinity and to be of the IgM isotype. Wands states that the other five were either of a different isotype or their affinities were not determined. (This latter statement also appears to contradict his statement that all 143 were "high binding".)

Wands argues that a "success rate of four out of nine", or 44.4%, is sufficient to support claims to the entire class. The Commissioner deems the success rate to be four out of 143, or 2.8%; to which Wands responds with statistical analysis as to how unlikely it is that Wands selected the only four out of 143 that worked. Wands did not, however, prove the right point. The question is whether Wands, by testing nine out of 143 (the Commissioner points out that the randomness of the sample was not established), and finding that four out of the nine had the desired properties, has provided sufficient experimental support for the breadth of the requested claims, in the context that "experi-

ments in genetic engineering produce, at best, unpredictable results", quoting from *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. and Int. 1986).

The premise of the patent system is that an inventor, having taught the world something it didn't know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution. Thus the specification and claims must meet the requirements of 35 U.S.C. §112. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 23-24 (CCPA 1970).

As the science of biotechnology matures the need for special accommodation, such as the deposit of cell lines or microorganisms, may diminish; but there remains the body of law and practice on the need for sufficient disclosure, including experimental data when appropriate, that reasonably support the scope of the requested claims. That law relates to the sufficiency of the description of the claimed invention, and if not satisfied by deposit, must independently meet the requirements of Section 112.

Wands is not claiming a particular, specified IgM antibody. He is claiming all such monoclonal antibodies in assay for hepatitis B surface antigen, based on his teaching that such antibodies have uniformly reproducible high avidity, free of the known disadvantages of IgM antibodies such as tendency to precipitate or aggregate. It is incumbent upon Wands to provide reasonable support for the proposed breadth of his claims. I agree with the Commissioner that four exemplars shown to have the desired properties, out of the 143, do not provide adequate support.

Wands argues that the law should not be "harsher" where routine experiments take a long time. However, what Wands is requesting is that the law be less harsh. As illustrated in extensive precedent on the question of how much experimentation is "undue", each case must be determined on its own facts. See, e.g., *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984); *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976); *In re Cook*, 439 F.2d 730, 734-35, 169 USPQ 298, 302-03 (CCPA 1971).

The various criteria to be considered in determining whether undue experimentation

is required are discussed in, for example, *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971); *In re Rainer*, 347 F.2d 574, 146 USPQ 218 (CCPA 1965); *Ex parte Forman*, 230 USPQ at 547. Wands must provide sufficient data or authority to show that his results are reasonably predictable within the scope of the claimed generic invention, based on experiment and/or scientific theory. In my view he has not met this burden.

Patent and Trademark Office Trademark Trial and Appeal Board

In re Johanna Farms Inc.

Serial No. 542,343

Decided June 30, 1988

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Prior adjudication — In general (§410.1501)

Trademark Trial and Appeal Board's prior decision upholding examiner's refusal to register proposed mark "La Yogurt" does not preclude registration of mark pursuant to subsequent application, since applicant, by presenting survey evidence and consumer letters regarding issue of how purchasers perceive proposed mark, has demonstrated that instant factual situation is different from situation presented in prior proceeding.

TRADEMARKS AND UNFAIR TRADE PRACTICES

2. Types of marks — Non-descriptive Particular marks (§327.0505)

Term "La Yogurt," with "yogurt" disclaimed, is registrable, since word "yogurt" is common English generic term rather than corruption or misspelling of French word for yogurt, since examining attorney failed to meet burden of showing clear evidence of generic use of mark as whole, and since evidence of record, including survey and consumer letters to applicant, demonstrates that primary significance of "La Yogurt" to majority of relevant public is that of brand name rather than generic term.

"Snuggle" bear, and Mattel's consistent intention to exploit public concern about the killing of baby seals in its marketing of "Snuggles the Seal" belies any desire to confuse the public by riding on "Snuggle" bear's coattails.

In addition, there is no evidence of actual confusion. Although such evidence would be highly probative of likelihood of confusion, its absence does not necessarily bar injunctive relief, where, as here, defendants have only been marketing their product for a short time. *Scarves by Vera*, 544 F.2d at 1175, 192 USPQ at 295. In the absence of positive evidence, however, this factor is a "wash."

Finally, the relatively high price of "Snuggles the Seal" and its marketing through upscale outlets suggests that it will be purchased by relatively sophisticated consumers, particularly in view of its promotion in connection with the "Save the Seals" campaign. Were plaintiff's mark stronger, or plaintiff's and defendant's products more similar, this factor alone might be insufficient to negate the likelihood of confusion. In view of the foregoing discussion, however, the comparative sophistication of defendant's customers militates against a finding of likelihood of confusion.

Application of the foregoing factors leads the court to the inescapable conclusion that plaintiff has failed to demonstrate a likelihood of consumer confusion between "Snuggles the Seal" and "Snuggle" bear. Lever possesses a strong trademark in a bear named "Snuggle" used for fabric softener, but only a weak mark in "Snuggle" as a name for a plush toy teddy bear. In view of significant differences in the names, physical appearances, and marketing of Lever's and Mattel's products, defendant is guilty of no infringement of plaintiff's weak mark.

Plaintiff's failure to show a likelihood of confusion means that he also lacks a likelihood of success on the merits and has failed to demonstrate irreparable harm. Moreover, while there are arguably serious litigable issues going to the merits, the balance of hardships does not tilt decidedly in Lever's favor. Any direct competition between the parties' products is primarily in the future and the harm to plaintiff's intended licensing program has been suggested only by the most speculative and conclusory testimony. In contrast, a preliminary injunction would do severe damage to Mattel's relationship with its customers and would render Mattel's investment in promoting the "Snuggles the Seal" name virtually worthless. Therefore, under all the relevant standards, plaintiff has failed to meet its burden in justifying a preliminary injunction.

For the foregoing reasons, plaintiff's motion for a preliminary injunction is denied.

Court of Appeals, Federal Circuit

DeGeorge v. Bernier

No. 84-1281

Decided July 19, 1985

PATENTS

1. Interference — Burden of Proof — Involving applicant and patentee (§41.055)

Board of Patent Interferences' statements indicating that copier "at least must show 'by clear and convincing evidence' that involved application supports its claims," and that "copier's burden also is perhaps beyond doubt," warrants finding that board improperly raised copier's burden of persuasion to "beyond a reasonable doubt," rather than "clear and convincing" standard.

2. Interference — Counts (§41.20)

Interference count that is arguably ambiguous as to whether it includes word processor, in addition to paragraph indent component, must be read broadly to exclude word processor, in view of patent specification's failure to show or describe in detail any kind of printer or data recording or play back mechanism.

3. Construction of specification and claims — Interference counts — In general (§22.501)

Board of Interference's finding of failure to meet best mode, which was influenced by board's erroneous count construction, was clearly erroneous.

Particular patents — Circuitry

3,579,193, Bernier, Editing and Revision System, award of priority against DeGeorge, application, reversed.

Appeal from Patent and Trademark Office Board of Patent Interferences.

Patent interference between Donald R. Bernier (Intel Corporation, real party in in-

BEST AVAILABLE COPY

terest), Patent No. 3,579,193, issued May 18, 1971, on application filed May 20, 1968, and Peter J. DeGeorge, Roger F. Ross, and Donald E. Sims (International Business Machines Corporation, real party in interest), application, Serial No. 228,733, filed Feb. 23, 1972, claiming benefit of application, Serial No. 871,424, filed Oct. 22, 1969, and application, Serial No. 606,670, filed Jan. 16, 1967. From award of priority to party Bernier, party DeGeorge et al. appeal. Reversed in part and vacated in part.

David W. Plant, and Fish & Neave, both of New York, N.Y. (Robert C. Morgan, Robert R. Jackson, and Douglas J. Gilbert, all of New York, N.Y., on the brief) for appellants.

Richard H. Smith, and Finnegan, Henderson, Farabow, Garrett & Dunner, both of Washington, D.C. (Richard L. Stroup, and Gerald L. Moore, both of Los Gatos, Calif., on the brief) for appellee.

Before Baldwin, Circuit Judge, and Skelton and Miller*, Senior Circuit Judges.

Baldwin, Circuit Judge.

This appeal is from a decision of the Board of Patent Interferences (board) of the United States Patent and Trademark Office (PTO) awarding priority of counts 1 through 13 to junior-party Bernier. We reverse in part and vacate in part.

Background

The senior-party appellants are Peter J. DeGeorge, Roger F. Ross, and Donald E. Sims (DeGeorge); the real party in interest is International Business Machines Corporation (IBM). The junior-party appellee is Donald R. Bernier (Bernier); the real party in interest is Intel Corporation (Intel).

The DeGeorge application, Serial No. 228,733 ('733), was filed February 23, 1972. It claims the benefit of DeGeorge application Serial No. 871,424 ('424), filed October 22, 1969, and DeGeorge application Serial No. 609,670 ('670), filed January 16, 1967. The specifications of all three applications can be considered identical for purposes of this appeal.

The interference was declared after DeGeorge copied, as counts 1 through 13, claims 28 through 40 of U.S. patent No. 3,579,193

('193) to Bernier, issued May 18, 1971 on an application filed May 20, 1968. The counts concern electrical circuitry in word processors (or typewriters) designed to obtain automatic indentation of a block or paragraph of text so that subsequent lines of the block (or paragraph) are indented from the left line regardless of the recorded codes for the subsequent lines. The invention, to be used with a word processor (or typewriter), was referred to by the board as a two-counter comparison paragraph indent (TCCPI) circuit.

Of the 13 counts, 2 through 13 are dependent and do not raise any issue distinct from those raised by independent count 1. All parties agree that the priority determination as to count 1 will govern the award of priority as to all counts. Count 1 reads as follows:

Apparatus for controlling the operation of a data processing system printer having printing mechanism for printing characters and functional mechanism for selecting the location of printing of characters, first means for sensing a first characteristic operation of the printer, second means enabled in response to the sensing of said first characteristic operation for counting a first succession of second characteristic functional operations including first storage means for storing the count of said second characteristic functional operation, comparison circuit means for counting a second succession of said second characteristic functional operations, and means limiting said second succession of second characteristic functional operations when the count of said second succession bears a preselected relationship to the count of said first succession of second characteristic functional operations.

To be successful in the interference, DeGeorge needs the benefit of the '670 filing date. Consequently, a critical issue is the sufficiency of the '670 disclosure with respect to enablement under 35 U.S.C. §112, paragraph 1.¹ Bernier contends that allegedly essential material contained in four United States patents, a United States patent application, and five IBM customer engineering

¹ To obtain the benefit of a parent filing date under 35 U.S.C. §120, the invention must be disclosed in the parent application "in the manner provided by the first paragraph of §112." The first paragraph of 35 U.S.C. §112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to take and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

* The Honorable Jack R. Miller assumed senior status effective June 6, 1985.

manuals was improperly incorporated by reference in the '670 application, and that the disclosure without those references, *i.e.*, the *per se* disclosure, was not enabling.

The board held, *inter alia*, that the burden of persuasion is on the copier DeGeorge, that the count language defines a combination of word processor and TCCPI circuit (as opposed to only a TCCPI circuit), that the '670 application was not enabling, and, hence, that DeGeorge was not entitled to the '670 filing date. The board also held that the DeGeorge applications did not include a "best mode contemplated by the inventor", also required by 35 U.S.C. §112 paragraph 1, and, *sua sponte*, that DeGeorge had not proven conception by all of the named three-person entity — DeGeorge, Ross, and Sims. Consequently, priority of invention was awarded to Bernier.

Issues

1. Whether the board imposed on DeGeorge the proper burden of persuasion.
2. Whether the board erred in its interpretation of count 1.
3. Whether the board erred in concluding that the DeGeorge '670 disclosure is not enabling.
4. Whether the board clearly erred in finding that the DeGeorge applications do not disclose the best mode.
5. Whether the board incorrectly ruled, *sua sponte*, that there was no conception by the three person entity of DeGeorge, Ross, and Simms.

OPINION

Improper Burden of Persuasion

Having copied the claims from Bernier's '193 patent, DeGeorge must show by clear and convincing evidence that the disclosure on which he relies supports the copied claims that became the interference counts. *Burson v. Carmichael*, 731 F.2d 849, 852, 221 USPQ 664, 666 (Fed. Cir. 1984); *Snitzer v. Etzel*, 531 F.2d 1062, 1063, 189 USPQ 415, 417 (CCPA 1976). As the party copying the claims, DeGeorge had the burden of persuasion on the right to make the counts which had to be met before an interference could properly be declared. That burden should be met by clear and convincing evidence. *Woods v. Tsuchiya*, 754 F.2d 1571, 1575, 225 USPQ 11, 13 (Fed. Cir. 1985).

DeGeorge argues that the board, instead of using the "clear and convincing" standard, used the "beyond a reasonable doubt" standard or at least equated that with the "clear and convincing" standard to the point that it affected the board's outcome. Bernier con-

tends that the board's discussion of "beyond a reasonable doubt" was made only in passing and not to describe the standard actually applied in the case.

[1] We agree with DeGeorge. The board stated that DeGeorge "at least must show 'by clear convincing evidence' that the involved application supports its claims corresponding to the counts." That burden, stated the board, "has been said to be a heavy one," and:

[1] It has been said further that there must be 'no doubt' that a copier's application discloses every material limitation and that 'all doubts must be resolved against the copier.' (Citation omitted.) Since all, presumably reasonable, doubts must be resolved against the copier, it would appear that the copier's burden also is perhaps beyond doubt. Also see *Marathon-Oil Co. v. Firestone* ... wherein ... it was stated ... [t]hese varying formulations of the burden of proof ("clear and convincing" and "beyond a reasonable doubt") do not ... compel different levels of proof.

From that, and other portions of the opinion, it is clear that the board raised the burden of persuasion to an improper level.

The "clear and convincing" standard is different from "beyond a reasonable doubt." See, *e.g.*, *In re Caveney*, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed. Cir. 1985); *Trans-World Manufacturing Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1559-60, 224 USPQ 259, 262 (Fed. Cir. 1984); *SSI/H Equipment S.A. v. USITC*, 718 F.2d 365, 380, 218 USPQ 678, 691 (Fed. Cir. 1983) ("Additional views of Circuit Judge Nies"); accord, *Addington v. Texas*, 441 U.S. 418, 423 (1979); *Woodby v. INS*, 385 U.S. 276, 284 (1966). Because the board applied an erroneous — and more difficult — standard of proof, the decision must at least be vacated. For the reasons indicated below, however, the board's decision is reversed in part and vacated in part.

Improper Count Construction

There are two asserted count interpretations. The board narrowly interpreted the count as requiring a word processor in addition to the TCCPI. DeGeorge urges a broader interpretation, which would require only the TCCPI. Under the narrower interpretation, the board found DeGeorge's grandparent '670 disclosure not enabling because of insufficient disclosure of a word processor embodiment.

A critical issue, therefore, is construction of the count, a question of law. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 127 (1984) (claim construction is a question of law). Interference counts

are given the broadest reasonable interpretation possible, and resort to the specification is necessary only when there are ambiguities inherent in the claim language or obvious from arguments of counsel. *See, e.g., Woods v. Tsuchiya*, 754 F.2d 1571, 1578, 225 USPQ 11, 15 (Fed. Cir. 1985); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 802 (CCPA 1981); *Kroekel v. Shah*, 558 F.2d 29, 32, 194 USPQ 544, 546 (CCPA 1977); *Stansbury v. Bond*, 482 F.2d 968, 974-75, 179 USPQ 88, 92 (CCPA 1973). If there is such ambiguity, resort must be had to the specification of the patent from which the copied claim came. *See, e.g., Burson v. Carmichael*, 731 F.2d 849, 852, 221 USPQ 664, 666 (Fed. Cir. 1984); *Sockman v. Switzer*, 379 F.2d 996, 1000, 154 USPQ 105, 106-07 (CCPA 1967).²

Here, the count is arguably ambiguous with respect to whether it includes a word processor (or typewriter) in addition to the TCCPI. The problem arises in large part from the use of "having" (in the second line of the quoted material below), and from a failure to include "comprising" before "first means" (below):

Apparatus for controlling the operation of a data processing system printer having printing mechanism for printing characters and function mechanism for selecting the location of printing of characters, first means . . . , second means . . . , comparison circuit means . . . , and means limiting (Emphasis added.)

"Comprising" is often used after a claim preamble to introduce elements of the invention. If "having" is viewed as a substitute for "comprising", the "printing mechanism . . . of characters," *i.e.*, word processor, might be viewed as an element of the claimed inven-

tion, not as part of the preamble. If, however, "having" is viewed as a participle combined with "printing mechanism . . . of characters", it would be an adjective phrase in the claim preamble modifying "data processing system printer", and the word processor would not be part of the claimed invention.³

[2] Resort to the '193 patent specification resolves the ambiguity compelling the broader reading of the copied claim, *i.e.*, without the word processor. The patent does not show or describe in reasonable detail any kind of printer, or data recording or playback mechanism with which the TCCPI feature may be used. The various electrical signals used as input signals to the TCCPI circuitry disclosed in the patent are received from a word processor with which the circuit is used. The circuitry for generating these signals resides in the word processor and is not described in the Bernier '193 patent except for a brief reference to it as being in a copending patent application.

We have often held that examining other claims in the patent may be used to determine the scope of the claim at issue, *see, e.g., McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 674, 221 USPQ 944, 950 (Fed. Cir.), *cert. denied*, 105 S. Ct. 514 (1984); *Lemelson v. United States*, 752 F.2d at 1549, 224 USPQ at 532, and our interpretation of the copied claim is harmonious with the other claims of the Bernier patent. In other Bernier independent claims (1, 21, and 41), just as in count 1, neither "comprising" nor "having" precedes the actual elements of the claimed invention. Though inclusion of such terms would have clarified all the claims, their absence does not render unreasonable our interpretation.

Even without resorting to the '193 patent, the broadest interpretation of the count is DeGeorge's, not the board's. As stated above, the broadest interpretation is always applicable so long as it is reasonable, and we conclude that interpreting the count as including

² Claims during prosecution, reissue and reexamination are also given the broadest reasonable interpretation possible, consistent with the specification. *See, e.g., In re Yamamoto*, 740 F.2d 1569, 222 USPQ 934 (Fed. Cir. 1984). That approach does not apply, however, during litigation of issued claims, where the specification and file history should be resorted to in ascertaining the claims' true meaning. *Lemelson v. United States*, 752 F.2d 1538, 1549, 224 USPQ 526, 532 (Fed. Cir. 1985); *Caterpillar Tractor Co. v. Berco, S.P.A.*, 714 F.2d 1110, 1114, 219 USPQ 185, 187 (Fed. Cir. 1983); *Autogiro Co. of America v. United States* 384 F.2d 391, 395, 155 USPQ 697, 702 (Ct. Cl. 1967), and claims are interpreted with an eye towards upholding their validity. *Carman Industries, Inc. v. Wahl*, 724 F.2d 932, 942-43, 220 USPQ 481, 489 (Fed. Cir. 1983); *ASC Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 932 (Fed. Cir. 1984).

³ Generally, and in this case, the preamble does not limit the claims. This case is unlike *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 896, 221 USPQ 669, 675-76 (Fed. Cir.), *cert. denied*, 105 S.Ct. 187 (1984), where preamble limitations were "necessary to give meaning to the claim and properly define the invention." *See generally Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 480 (CCPA 1951); 2 Chisum, Patents §8.06[1][d] (1985). *See also Arshall v. United States*, 621 F.2d 421, 430-31, 208 USPQ 397, 406-07 (Ct. Cl. 1980) (where effect of the preamble words are "at best ambiguous . . . a compelling reason must exist before the language can be given weight")

only the TCCPI is not only a reasonable interpretation, it is the *most* reasonable interpretation.

Modifiers of a term are usually in proximity to such term. The phrase "printing mechanism . . . of characters," is nearest the preamble term "printer" and thus likely would be understood to modify such term. Moreover, it is more reasonable to set off the preamble, *e.g.* with a comma as under our interpretation, than to have it run into the body of the claim without being set off, as true under the board's interpretation. Furthermore, the elements we perceive as part of the claimed invention are all labeled as "means" with a narrower functional description, whereas the phrase "printing mechanism . . . of characters" uses "mechanism for" instead of "means", thus enhancing that phrase's status as not being part of the claimed elements. In sum, the more reasonable claim interpretation is one having "printing mechanism . . . of characters" as part of the preamble modifying the term "data processing system printer" and not a limitation in the copied claim.

Enablement

Under the proper broad construction of the count, the DeGeorge *per se* disclosure adequately describes the TCCPI circuit for purposes of enablement under 35 U.S.C. §112. That construction compels us, therefore, to reverse the board's holding that the '670 *per se* disclosure is not enabling.

A patent must contain a description that enables one skilled in the art to make and use the claimed invention. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). "An inventor need not, however, explain every detail since he is speaking to those skilled in the art." *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981). "Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be." *In re Gay*, 309 F.2d 769, 774, 135 USPQ 311, 316 (CCPA 1962). "That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive." *Atlas Powder*, 750 F.2d at 1576, 224 USPQ at 413. See also *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir.), *cert. denied*, 105 S. Ct. 172 (1984); *In re Angstadt*, 537 F.2d 498, 503, 190 USPQ 214, 218 (CCPA 1976).

The board's enablement analysis was hampered by its erroneous interpretation of count 1 to include a word processor (as well as by its requirement that DeGeorge prove its case

beyond a reasonable doubt.) Though we could remand for the board to re-determine enablement in light of the proper count construction (and burden of proof), we choose to resolve the legal question of enablement, *Atlas Powder*, 750 F.2d at 1576, 224 USPQ at 413, and avoid unnecessary delay in determining priority between the parties.

Bernier has not seriously contested that the '670 disclosure encompasses all the components of the TCCPI. Indeed, the board held that the DeGeorge *per se* '670 disclosure showed all the elements of the TCCPI circuit. Bernier contends, however, that the *per se* '670 disclosure is not enabling because the control circuits for the connections and coils in the TCCPI circuit include contacts operated by coils in the word processor and the control circuits include connections with signals from the word processor that are not identified.

However, DeGeorge does disclose the portion of the preexisting device, *e.g.*, word processor, to be altered to accommodate the TCCPI circuit. DeGeorge need not disclose all circuit details of a word processor or the like. DeGeorge's expert witness Tanner, a graduate electrical engineer with years of design experience on word processors, testified that "any logic designer of a normal ability should be able to implement functions given this much description [in the *per se* '670 disclosure] about them." The *per se* disclosure specifically describes the TCCPI circuit input signals and their functions as found in an ordinary word processor. The TCCPI circuit relays are identified as to their functions and as to the functions and identity of the word processor signals required by them. No control circuits need be designed since these signal generating circuits exist in the word processor.

It is undisputed that counters, comparison circuits, and logic circuits for detecting input signals from a word processor were all familiar to those with skill in logic design, and particularly printer control logic design, in 1967. At that time, there was nothing exotic or unique about the logic elements of the TCCPI circuit and how they interfaced with signal generating control circuits in a word processor. Thus, there was no need to build a word processor from the ground up merely to implement the count.

DeGeorge not only disclosed the TCCPI circuit in block diagram format in the '670 application but also disclosed it in detailed schematic format within the same disclosure, together with an extensive verbal description. Because DeGeorge made this extra effort of added specific description, the board, in effect, penalized DeGeorge by stating: "[h]aving

chosen this narrow, species approach, we believe DeGeorge had an obligation also to reveal the specific wiring diagrams with which the TCCPI wiring diagrams were to interface sufficiently to complete all the control circuits [i.e., a whole word processor] in order to satisfy the statutory mandate. . . . We disagree with the board in that regard.

We conclude that the enablement requirement of §112 was satisfied by disclosure of detailed, *claimed* TCCPI circuitry without requiring detailed disclosure of all related, *unclaimed* circuitry with which the TCCPI might be interfaced.

Best Mode

"The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. §112. Best mode is a question of fact. *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 676, 221 USPQ 944, 951 (Fed. Cir.), *cert. denied*, 105 S. Ct. 514 (1984). Hence, our review of the board's best mode determination is under a clearly erroneous standard. *See, e.g., Coleman v. Dines*, 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed. Cir. 1985).

Not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant at the time of filing. *In re Gay*, 309 F.2d 760, 772-73, 135 USPQ 311, 315 (CCPA 1962). "[T]here is no objective standard by which to judge the adequacy of a best mode disclosure." *In re Sherwood*, 613 F.2d 809, 816, 204 USPQ 537, 544 (CCPA 1980). Instead, "only evidence of concealment (accidental or intentional) is to be considered. That evidence, in order to result in affirmance of a best mode rejection, must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment." *Id.* The purpose of the best mode requirement "is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived." *In re Gay*, 309 F.2d at 772, 135 USPQ at 315. Compliance with the best mode requirement exists when an inventor discloses his preferred embodiment *Id.*⁴

⁴ Here, the best mode determination is ancillary to priority in two contexts: with respect to the involved '733 application, *Tofe v. Winchell*, 645 F.2d 58, 209 USPQ 379 (CCPA 1981); and with respect to satisfaction of §112 by the parent application for purposes of entitlement to a parent date under 35 U.S.C. §120, *Weil v. Fritz*, 572 F.2d 856, 862-63, 196 USPQ 600, 603 (CCPA 1978). In *Magdo v. Kooi*, 699 F.2d 1325, 216 USPQ 1033 (Fed. Cir. 1983), however, this Court left open the

[3] The board found no best mode in the DeGeorge applications. The board's analysis, however, was influenced by its erroneous count construction. The board believed that "in order to comply with the best mode disclosure requirement of 35 U.S.C. §112, it was DeGeorge's responsibility to identify at filing the specific engineering level of MT/ST [word processor] with which it was contemplated that the disclosed species should be employed rather than [sic] some other level." Because the properly construed count does not include a word processor, failure to meet the best mode requirement here should not arise from an absence of information on the word processor. Hence, the board's finding of no best mode was clearly erroneous.

Conception by the Three Named DeGeorge Inventors

The board raised the issue of conception for the first time in its opinion. It held that DeGeorge did not prove that the three co-inventors, DeGeorge, Ross, and Sims, had "possession of conception."

Bernier regards the issue as moot on appeal because DeGeorge admits that it relies solely on its constructive reduction to practice (i.e., original filing date), not conception plus diligence until reduction to practice, for purposes of this appeal. As the board noted, Bernier raises no issue of the appropriateness of naming all three inventors in the DeGeorge applications. Indeed, Bernier concedes that DeGeorge is entitled to priority if its original '670 application satisfies 35 U.S.C. §112.

DeGeorge contends the issue is not moot because the board's erroneous, *sua sponte* ruling may cloud *ex parte* prosecution of the DeGeorge '733 application and any patent issuing on that DeGeorge application.

In light of our determination that the '670 application is enabling, and Bernier's concession of priority if DeGeorge is indeed entitled to the date of that application, DeGeorge is entitled to priority. We will not review the board's determination on conception. Though proper inventorship may be the subject of future prosecution, it is not ancillary to priority. *Coleman v. Dines*, 754 F.2d 353, 361, 224 USPQ 857, 863 (Fed. Cir. 1985); *Morgan v. Hirsch*, 728 F.2d 1449, 1452-53, 221 USPQ 193, 195 (Fed. Cir. 1984); *Case v. CPC International, Inc.*, 730 F.2d 745, 749, 221 USPQ 196, 200 (Fed. Cir.), *cert. denied*, 105 S. Ct. 223 (1984).

Conclusion

question of whether a best mode challenge to a patent in interference is ancillary.

The decision of the board is *reversed* on the enablement and best mode issues; it is *vacated* on the conception issue. Priority on all counts is awarded to DeGeorge.

REVERSED IN PART; VACATED IN PART

Ruthman, Feinberg & Dumas, Albany, N.Y., (Edward R. Feinberg, Albany, N.Y., of counsel) for plaintiff.

Heslin, Watts & Rothenberg, Latham, N.Y., (Robert E. Heslin, and Jeffrey Rothenberg, both of Latham, N.Y., of counsel) for defendants.

Miner, District Judge.

District Court, N.D. New York

Deats v. Joseph Swantak, Inc. et al.

No. 85-CV-36

Decided June 19, 1985

TRADEMARKS

1. Jurisdiction of courts — Trademarks (§43.55)

"Use in commerce" element which is required to establish federal trademark infringement jurisdiction must be specifically pleaded and cannot be read into complaint simply because trademark owner's contracts covered territory throughout U.S. and Canada, nor does mere incorporation into complaint of trademark registration create federal claim.

PATENTS

2. Jurisdiction of courts — Patent infringement (§43.45)

Accused patent infringers can rely, in seeking to remove case to federal court under 28 USC 1441(c), upon plaintiff's claim of unjust enrichment for breach of patent royalty agreement, since unjust enrichment question would have to be answered in context of federal patent law claim, but, since case was brought originally in state court which lacked jurisdiction over patent infringement claim, federal court acquired no jurisdiction on removal, and so patent claim must be dismissed.

Action by Richard A. Deats, against Joseph Swantak, Inc., and Joseph Swantak, for breach of contract, trademark and trade name infringement, breach of patent royalty agreement, and conversion. On plaintiff's motion to remand action to state court Motion granted in part

The instant action arises out of various commercial disputes surrounding a mobile hayfeeder patented by plaintiff Richard Deats in 1973 and sold under the federally registered trademark "Roll-A-Bout." Originally commenced in New York State Supreme Court, Schoharie County, the action was removed here by defendants on January 10, 1985 pursuant to 28 U.S.C. § § 1441(c), 1446.² Removal jurisdiction is asserted by defendants to be found in 28 U.S.C. § 1338(a)¹ and 15 U.S.C. § 1125(a) ("Lan-

¹ The Roll-A-Bout hayfeeder enjoys U.S. Patent No. 3,777,713, dated December 11, 1973. The description accompanying the patent filings notes that:

The invention relates generally to mobile animal feeders and, in particular, to an improved portable feeder of light weight construction and low cost.

Farmers have long desired a mobile, lightweight and inexpensive animal feeder and, particularly, an inexpensive cattle feeder which can be turned on its side and easily rolled to that portion of the farm where it is most needed. Previous animal feeders have not proved satisfactory and have not received significant commercial acceptance.

² 28 U.S.C. § 1441(c) provides:

(c) Whenever a separate and independent claim or cause of action, which would be removable if sued upon alone, is joined with one or more otherwise non-removable claims or causes of action, the entire case may be removed and the district court may determine all issues therein, or, in its discretion, may remand all matters not otherwise within its original jurisdiction.

The procedure to be followed in effecting removal is set forth in 28 U.S.C. § 1446.

³ 28 U.S.C. § 1338(a) provides:

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trade-marks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases